IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Sandra M. Simms	) DOCKET NO.:	3523/2/US
		)	
SERIAL NO.:	09/933,366	) GROUP ART UNIT:	1614
		)	
FILED:	August 20, 2001	) EXAMINER:	Cybille Delacroix-Muirheid

TITLE: SOLUTION COMPOSITION OF AN OXAZOLIDINONE ANTIBIOTIC DRUG HAVING ENHANCED DRUG LOADING

Commissioner for Patents
P.O. Box 1450
U.S. Patent and Trademark Office
Alexandria, VA 22313-1450

DECLARATION BY DR. SANDRA M. SIMS, UNDER 37 CFR 1.131

Sir:

I, Dr. Sandra Sims, declare that:

1. I am an inventor of the above-cited invention.
2. Prior to January 30, 2000, I had conceived and reduced the above-cited invention to practice in the United States, as evidenced by the following:
    a. Prior to January 30, 2000, having earlier conceived of an aqueous composition comprising an oxazolidinone antimicrobial drug in an effective concentration above the practical limit of solubility of the drug, and a pharmaceutically acceptable cyclodextrin compound in a concentration sufficient to maintain the drug in solution at such a concentration, I decided to investigate the feasibility of using one such cyclodextrin, sulfobutylether-β-cyclodextrin (Captisol™) to produce solutions of linezolid with effective concentrations above the practical limit of solubility of the drug.
    b. The results of the study described in (a) above were described in a Study Report, entitled "Feasibility Sudy of using Captisol™ to Lower the Injection Volume of Linezolid Sterile Solution." The report, an internal report, was produced prior to

January 30, 2000. A copy of the Summary page, summarizing the results of the study is attached hereto as an Exhibit.

c. The Summary page clearly shows that we were successful in producing solutions of linezolid containing Captisol™ that were above the practical limit of solubility of linezolid. Specifically, the Summary states that linezolid has a saturation solubility at ambient conditions of 2.9 +/- 0.1 mg/ml, and we produced solutions with concentrations of linezolid of 4.3, 9.5, 15.9, 22.1, 33.4, and 59.9 mg/ml, respectively.

3. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of an application or any patent issuing thereon.

Sandra M Sims — 24 May 2004

Dr. Sandra M. Sims — Date